BIOTRONIK Study Assesses Innovative Intracardiac Impedance Sensing Technology for CRT Optimization

New heart failure sensor expected to provide physicians with critical information about patients’ conditions and disease progression

BERLIN, Germany, November 28, 2012—BIOTRONIK, a leading manufacturer of innovative medical technology, today announced that the first patient has been enrolled in the company’s BIO.Detect HF II study. The study’s goal is to investigate the clinical relevance of the innovative intracardiac impedance (ICI) sensing technology and its ability to assess hemodynamic parameters. The ICI technology is incorporated in the company’s new cardiac resynchronization therapy defibrillators (CRT-D) which includes the innovative Lumax 740 HF-T. The ICI sensor evaluates changes in impedance during the cycle of the heart and is expected to be a useful surrogate for several left ventricular (LV) hemodynamic parameters.

The new technology is set to improve cardiac resynchronization therapy for heart failure patients. As the ICI technology is integrated into the device and will work with traditional leads, patients do not need to undergo any further complex or time consuming invasive procedures. Once clinically proven, this ICI sensor will form the basis for several unique algorithms for highly specific detection of worsening heart failure, automatic AV- and VV-delay optimization and intraoperative selection of optimal left ventricular lead placement.

“The BIO.Detect HF II study will evaluate whether hemodynamic changes can be used to inform physicians about changes in cardiac output—and whether these measurements can be put to work to optimize resynchronization therapy,” explained Professor Dr. Peter Søgaard of Aalborg University in Denmark, coordinating clinical investigator for the study. “These much anticipated study results will form a basis for the development of an algorithm for therapy optimization for cardiac resynchronization therapy defibrillator patients.”

The multicenter, international, nonrandomized interventional study spans 15 European investigational sites and is open to 60 patients. Each patient is implanted with a BIOTRONIK Lumax 740 HF-T device and is then tracked daily with BIOTRONIK Home Monitoring®. BIOTRONIK’s remote monitoring system is unique because it allows continuous, automatic, wireless monitoring of patient status and device status with daily updates that are independent of any patient interaction. The ICI data will be compared with data obtained by validated echocardiographic reference methods.
“Currently there is no reliable test that gives physicians sufficient time to intervene before a patient’s status becomes critical and the situation may result in acute hospitalization,” commented Dr. Klaus-Jürgen Gutleben, Heart and Diabetes Center, Bad Oeynhausen, Germany. “A continuous measurement of left ventricular volume would provide important information about disease progression and could be used to monitor heart failure and the optimization of CRT therapy.”

“Our ICI feature is just one of the innovations BIOTRONIK has recently developed to broaden the range of options physicians have for diagnosis and therapy—and offer patients the best care possible,” explains Christoph Böhmer, President International, BIOTRONIK. “BIOTRONIK’s new Lumax 740 ICDs and CRT-Ds also feature ProMRI® technology, which along with our Linoxsmart ICD leads represent the world’s first tachycardia system approved for magnetic resonance scanning. Add to that a device longevity of up to 11 years, our Lumax 740 implants truly make a difference and enhance patients’ quality of life.”

About BIOTRONIK SE & Co. KG
As one of the world’s leading manufacturers of cardiovascular medical devices, with several million devices implanted, BIOTRONIK is represented in over 100 countries by its global workforce of more than 5,600 employees. Known for having its finger on the pulse of the medical community, BIOTRONIK assesses the challenges physicians face and provides the best solutions for all phases of patient care, ranging from diagnosis to treatment to patient management. Quality, innovation and reliability define BIOTRONIK and its growing success—and deliver confidence and peace of mind to physicians and their patients worldwide.

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Upon publication, please provide us with a copy.